K011354

JUL 3 1 2001

510(k) Summary

Submission

Submitted by:
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Application Preparor:
(contact for additional information)
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Date of preparation: April 27, 2001

Device

Common Name: Metallic bone fixation device
Trade Name: High Tibial Osteotomy Plating System
Classification Name: KTT, Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component

Predicate Device: Arthrex Puddu Osteotomy System, K973812

Description and Intended Use

The dj Orthopedics HTO Plating System like the predicate device, includes, right, left, accessories and instruments. Bone screws enable the plate to be coupled to bone by securing the screws for the intended use. The various components within the system are provided to accommodate various anatomies and injuries.

Intended Use:

The dj Orthopedics HTO Plating System is intended for use as an adjustable fixation device used in opening-wedge osteotomy for treatment of bone and joint deformities and misalignment caused by injury or disease such as arthritis and osteoporosis.

Technological Characteristics

Feature	***HTO Plating System***	***Arthrex Puddu Osteotomy System***
Plates	Implantable	Implantable
Screws	Implantable	Implantable
Material	Surgical Grade Stainless Steel 316L	Surgical Grade Stainless Steel 316L

Conclusion

The device and the predicate device have similar design characteristics and intended use. The new device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2001

Mr. Jim Arganda
Director, Regulatory Affairs/Quality Assurance
dj Orthopedics, LLC
2985 Scott Street
Vista, California 92083

Re: K011354
Device Name: High Tibial Osteotomy Plating System
Regulation Number: 888.3030
Regulatory Class: II
Product Code: HRS
Dated: May1, 2001
Received: May 3, 2001

Dear Mr. Arganda:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Ver/ 3 - 4/24/96

Applicant: dj Orthopedics, LLC

510(k) Number (if known): K011354

Device Name: High Tibial Osteotomy Plating System

Indications For Use:

The High Tibial Osteotomy Plating System is intended to be used in conjunction with bone screws to provide fixation following opening wedge osteotomies in long bones.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011354